IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA ALEXANDRIA DIVISION

ADVANCED LITHIUM ELECTROCHEMISTRY (CAYMAN) Co. Ltd., and ADVANCED LITHIUM ELECTROCHEMISTRY CO., LTD.,

Declaratory Judgment Plaintiffs,

v.

HYDRO-QUEBEC; CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE; UNIVERSITE DE MONTREAL; and LIFEPO4+C LICENSING AG,

Declaratory Judgment Defendants.

Case No. 1:24-cv-01421-RDA-WBP

<u>DEFENDANTS' REPLY IN SUPPORT OF THEIR RENEWED MOTION TO DISMISS</u> FOR FAILURE TO STATE A CLAIM

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I. INTRODUCTION

Plaintiffs ask this Court to break new ground and expand the obviousness-type double patenting doctrine to invalidate an earlier-filed patent based upon a later-filed patent that claims the same priority date. Notably, at no point in their Opposition (Dkt. No. 36) do Plaintiffs cite a single case holding that a later, or even co-filed, post-URAA patent can qualify as an OTDP reference. Instead, Plaintiffs spend pages providing irrelevant "context" all while failing to address the fundamental legal flaw in their argument.

The issue is not whether PTA should be considered in assessing expiration dates, (*see* Dkt. No. 36 at 7-9), the general history of the OTDP doctrine, (*id.* at 4-6), or whether expiration dates are relevant to the analysis, (*id.* at 13-14). Rather, the issue is whether a patent must be earlier-filed to qualify as a proper OTDP reference where the challenged patent shares the same priority date. Defendants have cited Federal Circuit guidance and the decision of a sister court that answers this question in the affirmative. *See, e.g., In re: Cellect, LLC*, 81 F.4th 1216, 1230 (Fed. Cir. 2023) ("[Patent claims] are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of *earlier-filed, commonly owned claims.*"); *Allergan USA, Inc. v. MSN Lab'ys Priv. Ltd.*, 111 F.4th 1358, 1369 (Fed. Cir. 2024) ("[A] first-filed, first-issued, later-expiring claim *cannot be invalidated by a later-filed*, later-issued, earlier-expiring reference claim having a common priority date.")¹; *Acadia Pharms. Inc. v. Aurobindo Pharma*

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¹ As discussed in Defendants' Motion (Dkt. No. 33-1 at 7-10), while the challenged patent in *Allergan* also issued earlier than the purported reference patent, that does not change the necessity of dismissal here where only post-URAA patents with the same priority are at issue and the reference patent is not earlier-filed. As courts have recognized, issuance dates—as contrasted with filing dates—provide a poor barometer for assessing obviousness-type double patenting for post-URAA patents. *See Gilead Scis., Inc. v. Natco Pharma Ltd.*, 753 F.3d 1208, 1215-16 (Fed. Cir. 2014) ("[I]f the double patenting inquiry was determined by issuance date for post-URAA patents, there could be a significant difference in an inventor's period of exclusivity over his invention (and its obvious variants) based on mere days' difference in the issuance of several patents to the

Ltd., 706 F. Supp. 3d 477, 488 (D. Del. 2023) ("Because a patent must be earlier-filed to be available as an OTDP reference, the Court finds that the '271 patent does not qualify as a proper reference against the '740 patent.") (emphases added). Plaintiffs have cited no cases that state the contrary. Plaintiffs' refusal to engage with the issue at hand evinces the weakness of their Opposition and their failure to state a claim.

II. ARGUMENT

A. Plaintiffs Fail to Establish a Legally Cognizable Claim for Patent Invalidity Pursuant to the OTDP Doctrine.

As an initial matter, it bears noting that Plaintiffs blur the lines between two distinct doctrines: statutory double patenting (also called "same invention" double patenting) and non-statutory double patenting (also called obviousness-type double patenting or OTDP). Statutory double patenting springs directly from 35 U.S.C. § 101 and says that a patentee may only obtain "a patent" for the <u>same</u> invention. *See In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997) ("Same invention" double patenting is based upon 35 U.S.C. § 101 [], which states that an inventor may obtain 'a patent' for an invention."); *see also In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985) ("[T]he term 'same invention,' . . . means an invention drawn to identical subject matter."). Unlike the statutory double patenting doctrine that is expressly authorized by Congress, obviousness-type double patenting is a judicially-created doctrine that says a patentee also cannot obtain a second patent on <u>an obvious variation</u> of a first patent without disclaiming additional claim term the second patent would otherwise receive. *See Lonardo*, 119 F.3d at 965 ("Obviousness-type double patenting, on the other hand, is judicially created and prohibits an inventor from obtaining a second

inventor.... Such significant vacillations in an inventor's period of exclusivity over his invention and its obvious variants [based on issuance date] is simply too arbitrary, uncertain, and prone to gamesmanship."); *Acadia*, 706 F. Supp. 3d at 488 ("Like expiration dates, but unlike issue dates, filing dates are not prone to gamesmanship.").

patent for claims that are not patentably distinct from the claims of the first patent. With obviousness-type double patenting, however, a terminal disclaimer may overcome that basis for unpatentability[.]"). The difference is not immaterial.

Plaintiffs allege only invalidity based on obviousness-type double patenting. Critically, it is Plaintiffs' burden to plead a legally cognizable claim. *See, e.g., Santini v. Rucker*, No. 3:22-cv-370-DJN, 2022 WL 17417165, at *5 (E.D. Va. Dec. 5, 2022) ("The facts alleged must be sufficient to 'state all the elements of any claims.") (quoting *Bass v. E.I. Dupont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir. 2003)) (internal marks omitted). Furthermore, "[t]he court need not accept the plaintiff's legal conclusions drawn from the facts, nor need it accept as true unwarranted inferences, unreasonable conclusions, or arguments." *Carfax, Inc. v. Accu-Trade, LLC*, No. 1:21-cv-00361-RDA-TCB, 2022 WL 657976, at *3 (E.D. Va. Mar. 4, 2022) (citing *Wahi v. Charleston Area Med. Ctr., Inc.*, 562 F.3d 599, 616 n.26 (4th Cir. 2009)) (internal quotations and marks omitted).

By statute, issued patents are presumed valid and entitled to their full congressionally guaranteed terms. *See* 35 U.S.C. § 282(a) ("A patent shall be presumed valid."); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 958 (Fed. Cir. 1997) ("The purpose of the presumption of validity, codified at 35 U.S.C. § 282, is to contribute stability to the grant of patent rights."). Patent Term Adjustments (PTA), like the standard terms for issued patents, are granted pursuant to statutory provisions passed by Congress. *See* 35 U.S.C. §§ 154(a) (providing for a 20-year term from earliest filing), 154(b) (providing "Patent Term Guarantees"). The obviousness-type double patenting doctrine, in contrast to statutory double patenting, is a limited judicially constructed carve out to these statutorily guaranteed patent rights. For Plaintiffs to establish that they have a legally cognizable claim for invalidity of the duly issued U.S. Patent No. 7,601,318 (the "'318 Patent" or

"challenged patent"), they must plead facts establishing that the OTDP doctrine applies to the circumstances at hand here. Specifically, Plaintiffs must show that U.S. Patent No. 7,285,260 (the "'260 Patent" or "purported reference patent") is a proper reference patent for the OTDP analysis. As Defendants explained in their Motion (Dkt. No. 33-1), and as evidenced by Plaintiffs' Opposition, Plaintiffs are unable to make this showing because the '260 Patent is not filed earlier than the '318 Patent².

B. Plaintiffs' Cherry-Picked Dicta Does Not Create a Legally Cognizable Claim.

Plaintiffs are correct that the Federal Circuit has recognized that a purpose of the OTDP doctrine is "to prevent an *unjustified* timewise extension of patent exclusivity beyond the life of a patent." *Allergan*, 111 F.4th at 1367 (emphasis added). Defendants recognized as much in their Motion. *See* (Dkt. No. 33-1 at 8-9); *see also Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, 909 F.3d 1355, 1367 (Fed. Cir. 2018) (recognizing an unjustified extension where the applicant "claim[ed] different effective filing dates for different patents to extend the life of patent exclusivity"); *Allergan*, 111 F.4th at 1371 ("*Abbvie* is a prime example of the post-URAA scenario we contemplated in *Gilead* where an inventor, seeking to prolong his exclusivity rights over his invention, applies for a second patent on an obvious variant of his invention protected by a first patent and achieves a later expiration date by choosing a different, later priority date than the one relied upon for the first patent.") (internal quotations omitted); *In re Fallaux*, 564 F.3d 1313, 1318 (Fed. Cir. 2009) (acknowledging "that the unjustified patent term extension justification for obviousness-type double patenting has limited force [post-URAA]... in no small part because of

² This case does not involve a purported reference patent under OTDP with a different priority or effective filing date than the challenged patent. *See* (Dkt. No. 33-1 at 8-9). It is undisputed that the '318 Patent and '260 Patent have the same priority and effective filing date. *See id.*; *see also* (Dkt. No. 36 at 2-3).

the change in the Patent Act from a patent term of seventeen years from issuance to a term of twenty years from filing").

However, there is nothing "unjustified" about the '318 Patent merely receiving its full term, including congressionally-mandated PTA due to USPTO delays. Plaintiffs do not allege that Defendants engaged in any nefarious actions during prosecution.³ While Plaintiffs repeatedly reference the "unjustified extension" language from *Allergan* and *Cellect* throughout their Opposition, Plaintiffs' interpretation of that amorphous policy concern does not establish a legally recognized claim. Courts need not engage in divination to determine what constitutes an "unjustified extension"; rather, they can rely on the established guidance of the Federal Circuit, which provides that a patent must be earlier-filed to qualify as an OTDP reference patent. *See Cellect*, 81 F.4th at 1230 ("[Patent claims] are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of *earlier-filed*, *commonly owned claims*."); *Allergan*, 111 F.4th at 1369 ("[A] first-filed, first-issued, later-expiring claim *cannot be invalidated by a later-filed*, later-issued, earlier-expiring reference claim having a common priority date."); *see also Acadia*, 706 F. Supp. 3d at 488 ("putative OTDP references *must be earlier-filed* to be available as a reference") (emphases added).

Plaintiffs' slippery-slope argument that "patent applicants would jump on a patent-application-filing frenzy and . . . fil[e] overlapping patent applications minutes or hours earlier to exploit the alleged loophole and game our patent system," while an entertaining visual, finds no basis in reality. (Dkt. No. 36 at 3; *see also id.* at 14). First, it is unclear how patent applicants would "game our patent system" by filing applications "minutes or hours earlier"—namely, Plaintiffs fail

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³ Indeed, Plaintiffs dropped their flawed inequitable conduct claim that relied upon literally false factual allegations as evidenced by the public record. *See* (Dkt. No. 24 (Memorandum in Support of Dkt. No. 23 Motion to Dismiss) at 5-17); (Dkt. No. 25 (First Amended Complaint)).

to explain *what* these applications are earlier than or how this would differ from current practice. No matter how many applications an applicant files, there will always be only one earliest-filed application. Indeed, if applicants engaged in this "patent application-filing frenzy," and it resulted in more than one patent on obvious variations of a single invention, then the *later-filed* patents may very well be subject to OTDP over the *first-filed* patent.⁴ Despite Plaintiffs' claims to the contrary, no parade of horribles results from the "earlier-filed" requirement.

C. Plaintiffs' Discussion of the Case Law Confirms That No Legally Cognizable Claim Exists.

1. Plaintiffs' Re-Writing of Cellect Ignores the Court's Reasoning and the Facts at Issue in that Case

Defendants do not "ignore the actual holding and analysis in [Cellect]," as Plaintiffs contend. (Dkt. No. 36 at 7). Cellect's ultimate holding—that PTA is factored into the expiration dates before conducting the OTDP analysis—is not disputed. See (Dkt. No. 33-1 at 6; Dkt. No. 36 at 5). However, Plaintiffs' argument regarding Cellect's holding misses the mark. As the Federal Circuit explicitly noted in Allergan, "the patent owner in Cellect did not challenge whether the reference claims used to invalidate the asserted claims were proper ODP reference claims," and "the court did not consider that issue." Allergan, 111 F.4th at 1369 n.6; see also Acadia, 706 F. Supp. 3d at 487 ("Cellect opted not to challenge the availability of the reference patents being used in an OTDP challenge, and 'instead focused its argument on whether or not O[T]DP could cut short a grant of PTA."") (quoting Cellect, 81 F.4th at 1222). As such, Cellect did not consider the issue of whether a purported reference is a proper OTDP reference. Plaintiffs ignore this important fact, choosing instead to obfuscate the issue by discussing irrelevant portions of Cellect.

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⁴ See Allergan, 111 F.4th at 1371 (explaining that "it is unsurprising that prosecution of a first-of-its-kind invention can be protracted, requiring greater time and effort by the applicant and examiner alike, such that any eventual patent on that invention is awarded some amount of PTA").

Plaintiffs also ignore *Cellect's* guidance that patent claims "are entitled to their full term, including the duly granted PTA, unless they are found to be *later-filed* obvious variations of *earlier-filed*, commonly owned claims," apparently determining that the Court simply misspoke. *Cellect*, 81 F.4th at 1230 (emphasis added). That is misguided. First, the portion referenced by Plaintiffs as "dicta" is not the only time the *Cellect* Court discussed the "earlier-filed" requirement for an OTDP reference patent. *See also id.* at 1226 ("ODP [is] a doctrine that limits the term of a patent or, at least, ties *later-filed*, commonly owned, obvious variations to the expiration date of an *earlier-filed* reference patent.") (emphasis added). Furthermore, the *Allergan* Court specifically acknowledged the referenced portion of *Cellect* as the Federal Circuit's "case law" on this issue:

Despite Sun's assertions to the contrary, our conclusion is consistent with *our case law*. *E.g.*, *Cellect*, 81 F.4th at 1230 ("We do, however, note that the non-asserted claims in the challenged patents are entitled to their full term, including the duly granted PTA, unless they are found to be later-filed obvious variations of *earlier-filed*, commonly owned claims.").

Allergan, 111 F.4th at 1370 (emphasis added). Plaintiffs may wish to dispose of the Federal Circuit's jurisprudence where inconvenient for them, but that desire does not make it so.

2. Plaintiffs' Selective Quoting of Allergan Cannot Re-Write the Facts of That Case or Those at Issue Here

Plaintiffs' assertion that Defendants merely "rely on a single sentence [of *Allergan*], while ignoring paragraphs of legal analysis" is difficult to square with Defendants' Motion and *Allergan* itself. First, the "single sentence" that Plaintiffs seek to cast aside is *the express holding of Allergan*. See (Dkt. No. 33-1 at 6 (citing *Allergan*, 111 F.4th at 1369 ("We therefore hold that first-filed, first-issued, later-expiring claim cannot be invalidated by a later-filed, later-issued, earlier-expiring reference claim having a common priority date.") (emphasis added))).

Second, Plaintiffs' selective quotations from *Allergan* ignore relevant details as well as the Court's underlying reasoning. For instance, Plaintiffs contend that *Allergan* stands for the

proposition that "the 'first-issued patent' [] 'sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants." (Dkt. No. 36 at 10 (quoting Allergan, 111 F.4th at 1369)). However, Plaintiffs' quotation omits the critical words "first-filed" in that sentence. See Allergan, 111 F.4th at 1369 ("As the *first-filed*, first-issued patent in its family, it is the patent that sets the maximum period of exclusivity for the claimed subject matter and any patentably indistinct variants.") (emphasis added). While Plaintiffs' proposition may be correct for pre-URAA patents, it is *not* accurate for post-URAA patents whose period of exclusivity is based on the filing date. Indeed, the Federal Circuit in *Gilead* explicitly recognized that the period of exclusivity for post-URAA patents is keyed from "the filing date of the earliest application." Gilead, 753 F.3d at 1214-15 ("In the URAA, Congress clearly limited the one period of exclusivity an inventor can obtain for each of his inventions to twenty years from the *filing date of the earliest application*... with some limited exceptions.") (emphases added). Although Gilead specifically addressed the roles of issuance and expiration dates in OTDP analysis, subsequent Federal Circuit decisions, such as Novartis and Abbvie, repeatedly recognized the importance of filing dates in OTDP analysis of post-URAA patents. See (Dkt. No. 33-1 at 8-9 (citing Novartis, 909 F.3d at 1367 (addressing differing effective filing dates) and Abbvie Inc. v. Mathilda & Terence Kennedy Institute of Rheumatology Trust., 764 F.3d 1366, 1369-71 (Fed. Cir. 2014) (addressing differing priority dates))).

Allergan itself provides a succinct explanation—through the example of parent and child applications—as to why Plaintiffs' position would "not only run afoul of the fundamental purposes of ODP, but effectively abrogate the benefit Congress intended to bestow on patentees when codifying PTA":

[S]uch a holding would require patent owners, in order to preserve the validity of the [first-filed] parent patent, to file a terminal disclaimer disclaiming any term of the [first-filed] parent that extends beyond that of the [second-filed] child, which, given that the patents share a priority date, would amount to the disclaimer of *only* PTA. That [first-filed] parent patent, then, would not receive the benefit of its congressionally guaranteed patent term, *see* 35 U.S.C. § 154(b), and would instead be limited to the, presumably shorter, term of its own [second-filed] child. Such a result would be untenable.

Allergan, 111 F.4th at 1371. Despite Allergan's admonition to the contrary, Plaintiffs ask this Court to use a second-filed patent (the '260 Patent) to ensure that a first-filed patent (the '318 Patent) sharing the same priority date will "not receive the benefit of its congressionally guaranteed patent term." *Id.* That is improper.

Similarly, Plaintiffs' argument that "the rationale of *Allergan* [placed] emphasis on the date of patent issuance" (Dkt. No. 36 at 13), as opposed to the filing date, is in direct contrast with the decision itself. Indeed, as discussed below, the Court in *Allergan* distinguished the holding of *Gilead* on the express basis that it "did not address the role of filing dates." *See Allergan*, 111 F.4th at 1370. Notably, outside of their selective quotations that omit words like "first-filed," Plaintiffs are unable to point to any instances of *Allergan* placing "emphasis on the date of patent issuance" as opposed to the filing date. Indeed, it does not, nor should it, as *Allergan* dealt with post-URAA patents.

3. Plaintiffs' Have No Substantive Response to Judge Williams' Reasoning in Acadia

Plaintiffs are correct that *Acadia* "appears to announce Defendants' [position]," that *Acadia* "is consistent with *Allergan*," and that *Acadia* relied upon the same portions of *Cellect* as Defendants. (Dkt. No. 36 at 11-12). However, that is where the accuracy of Plaintiffs' discussion ends. Undeterred by the unambiguous reasoning of *Acadia* that "only earlier-filed patents are proper [OTDP] references," Plaintiffs jump through hoops to rewrite Judge Williams's opinion because they believe it would "benefit" from their skewed interpretation of *Allergan*.

Plaintiffs emphasize the following language from *Acadia* as purportedly "confirm[ing] why the ODP doctrine is applicable here":

That only earlier-filed patents are proper references is equitable, since the purpose of OTDP doctrine is to "prevent a patent owner from extending his exclusive rights to an invention through claims in a later-filed patent that are not patentably distinct from claims in the earlier-filed patent." *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009); see also Cellect, 81 F.4th at 1226 (OTDP "limits the term of a patent or, at least, ties later-filed commonly owned, obvious variations to the expiration date of an earlier-filed reference patent."). If a later-filed patent is used as a reference, the logic and purpose of OTDP is flipped on its head: rather than preventing a patent owner from unjustifiably extending the term of a patent, OTDP would operate to cut off a patent term that would have been valid but for a later-filed patent.

(Dkt. No. 36 at 12 (quoting Acadia, 706 F. Supp. 3d at 487) (emphasis added by Plaintiffs)). It is difficult to understand how such unequivocal language supports Plaintiffs' position that a later-filed patent can be a proper OTDP reference. Plaintiffs certainly provide no such explanation. Instead, Plaintiffs contend that Judge Williams' reasoning is "flawed" because "the period of exclusivity is defined by the time period between patent issuance and patent expiration." (Dkt. No. 36 at 12). Notably, that position is unaccompanied by any case citation. As discussed above, Plaintiffs' proposition may be correct for pre-URAA patents, but it is *not* accurate for post-URAA patents. See Gilead, 753 F.3d at 1214-15 ("In the URAA, Congress clearly limited the one period of exclusivity an inventor can obtain for each of his inventions to twenty years from the filing date of the earliest application... with some limited exceptions.") (emphasis added); see also Acadia, 706 F. Supp. 3d at 481 ("[A] U.S. patent issued on an application filed on or after June 8, 1995 has a patent term that 'end[s] 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application or applications ..., from the date on which the earliest such application was filed."") (quoting 35

U.S.C. § 154(a)(2) (emphasis added)). As such, Plaintiffs' attempt to explain away Judge Williams' reasoning in *Acadia* as "flawed" is misguided and without support.

4. Plaintiffs' Arguments with Respect to Gilead Are Not Only Irrelevant but Misleading

Plaintiffs' discussion with respect to *Gilead*—like the rest of the Opposition—misses the point. Defendants do not dispute that the '318 Patent expires later than the '260 Patent due to the greater amount of PTA awarded. Defendants also do not dispute that *if* the '260 Patent was filed earlier than the '318 Patent, then the difference in expiration dates could qualify the '260 Patent as a proper OTDP reference. However, those are *not* the facts at issue here.

Plaintiffs' citation to *Gilead*'s statement that "[p]ermitting any earlier expiring patent to serve as a double patenting reference for a patent subject to the URAA guarantees a stable benchmark" is purposefully misleading. (Dkt. No. 36 at 13 (quoting *Gilead*, 753 F.3d at 1216)). The standard for OTDP is not merely that "any earlier expiring patent [can] serve as a double patenting reference." Indeed, the Federal Circuit in *Allergan* explicitly explained that *Gilead* does not stand for the simple proposition that "later-issued, earlier-expiring claims [can be] relied upon as ODP references to invalidate [an] earlier-issued but later-expiring claim," and specifically identified that *Gilead* did not deal with the issue here—filing dates:

We acknowledge Sun's position that our holding in *Gilead* appears to apply here, where the later-issued, earlier-expiring claims of the '011 and '709 patents are relied upon as ODP references to invalidate the earlier-issued but later-expiring claim of the '356 patent. But the court in *Gilead*, guided by the parties' arguments, focused its inquiry only on whether issuance dates should remain the most relevant benchmark for evaluating ODP post-URAA. *See id.* at 1214–15. **It did not address the role of filing dates**. And most importantly, our holding in *Gilead*, which was expressly limited to the "circumstances of [that] case," *id.* at 1212, was not pronounced in a vacuum. Unlike here, the challenged claims of the asserted patent in *Gilead* were filed after, claimed a later priority date than, *and* expired after the reference claims, which resulted in an unwarranted extension of patent term for an invention that had already been the subject of an earlier-filed, earlier-expiring claim.

Allergan, 111 F.4th at 1370 (first emphasis added, second emphasis in original). Indeed, the Court

in Allergan found that none of the earlier-expiring patents could qualify as reference patents for

the OTDP analysis. Plaintiffs' half-hearted misinterpretation of the proper legal standard misses

the mark by failing to consider the role of filing dates and priority dates.

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their

Renewed Motion to Dismiss and dismiss Plaintiffs' First Amended Complaint with prejudice.

Dated: February 3, 2025

/s/ April E. Weisbruch

April E. Weisbruch (Va. Bar No. 79191)

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CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2025, the foregoing was filed electronically and served on all counsel of record.

/s/ April E. Weisbruch
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